Section 1: Device Name

Common or Usual Name:	Electromyograph, Diagnostic
Proprietary Model Name:	CWAS 100
Regulation Name:	Electromyograph, Diagnostic
Regulation Number:	21 CFR 890.1375

Section 2: Indications for Use

The CWAS 100 is a non-invasive, multi-modality physiologic monitoring device. The device measures several physiologic signals, and its software generates a report.

The CWAS 100 measures the following physiologic signals:

- Bilateral differences in surface EMG along the spine
- Heart Rate
- Skin temperature
- Galvanic Skin Resistance
- Body fat percentage in subjects eighteen years and older

Section 3: Device Description

The CWAS 100 is a non-invasive, multi-modality physiologic monitoring device. The CWAS 100 contains the following five sensor types: (1) surface EMG, (2) IR Plethsmograph, (3), Skin temperature, (4) Galvanic Skin Resistance and (5) IR Body Composition Analyzer.

Hardware

The CWAS 100 hardware consists of an instrument console and five different sensor types. All five sensor types plug directly into the front panel of the CWAS 100 Instrument Console. The CWAS 100 Console is powered via a UL2601 listed power supply. The Instrument Console is connected to a personal computer (IBM compatible) via an isolated USB port connection.

Software

The CWAS 100 software displays real-time surface EMG, heart rate, skin temperature, Galvanic Skin Resistance, and Body Composition, allowing the user to ensure that readings are stable prior to data collection. The CWAS 100 software allows the user to: (1) enter patient information, (2) record surface EMG, heart rate, skin temperature, Galvanic Skin Resistance, and Body Composition, and (3) print out a data report which summarizes the results of the above sensors as well as blood pressure, vital lung capacity, and chest, leg and back strength, which are data provided by the user.

Section 4: Predicate Device

The CWAS 100 is an expansion of the Insight Millennium III, a device that we have previously registered with FDA. The CWAS 100 differs from the Insight Millennium III in the following manners:

1. Hardware: Addition of two new sensors, and the elimination of two previous sensors.

2. Software: The Insight Millennium III software has been modified to: (1) add the display and reporting functionality for the two new CWAS 100 sensors, (2) remove the display and reporting functionality for the two eliminated Insight Millennium III sensors, and (3) add the functionality to have the user enter other physiologic data about the patient, and incorporate this information into the reporting function.

The balance of this section documents the substantial equivalence of CWAS 100 to the following three products:

Manufacturer	Predicate Device Name	510(k) Number
Insight Millennium III	Fasstech	K023209
Biofeedback System/3	Davicon	K914920
Futrex 6100/XL	Futrex, Inc.	K963271

The CWAS 100 is equivalent to these legally marketed devices in the following ways:

- The physical characteristics and electrical characteristics (performance characteristics) of the CWAS 100 are equivalent to the Insight Millennium III. The only difference is the addition of two sensor types (Galvanic Skin Resistance and IR Body Composition Analyzer), and the elimination of two sensors that were part of the Insight Millennium III (Algometer and Inclinometer).
- The physical characteristics and electrical characteristics (performance characteristics) of the CWAS 100 Galvanic Skin Resistance sensor is equivalent to the Biofeedback System/3 Galvanic Skin Resistance sensor
- The CWAS 100 IR Body Composition Analyzer sensor is the Futrex 6100/XL sensor. This sensor is registered with FDA, and has been combined with the CWAS 100 for user convenience.

The CWAS 100 differs from these legally marketed devices in the following ways:

- The device types listed above have been combined for reasons of user convenience.
- The CWAS 100 data report combines a variety of physiologic data for user convenience.

Predicate Device Comparison Chart

Component	Feature	CWAS 100	Insight Millennium III	Futrex 6100	Biofeedback System/3
Surface EMG		**Yes**	Yes	N/A	N/A
	Calibrated Range	**0.1 – 999 uV**	0.1 – 999 uV	N/A	N/A
	Common Mode Rejection	**150 dB**	150 dB	N/A	N/A
	Bandwidth	**20-500 Hz (50/60 Hz notch)**	20-500 Hz (50/60 Hz notch)	N/A	N/A
Skin Temperature		**Yes**	Yes	N/A	N/A
	Calibrated Range	**55°F - 120°F**	55°F - 120°F		
	Accuracy	**±0.2°F nominal**	±0.2°F nominal		
IR Plethsmograph		**Yes**	Yes	N/A	N/A
	Output Voltage	**5 – 50 mV, typical at rest**	5 – 50 mV, typical at rest	N/A	N/A
	Output Impedance	**1 kΩ, nominal**	1 kΩ, nominal	N/A	N/A
Instrument Console					
	Output	Isolated USB	Isolated USB	N/A	N/A
	A/D converter	16 bit, 16 channel	16 bit, 16 channel	N/A	N/A
	Controls	None	None	N/A	N/A
	Indicators	Rear Panel: Green LED Power Indicator Front Panel: Green LED PC connect Indicator	Rear Panel: Green LED Power Indicator Front Panel: Green LED PC connect Indicator	N/A	N/A
	Power	12 VDC, 28 W converter, internal.	12 VDC, 28 W converter, internal.	N/A	N/A
	Physical	3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz	3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz	N/A	N/A
Range of Motion Sensor		**No**	Yes	N/A	N/A
Algometer		**No**	Yes		
IR Body		**Yes**	N/A	Yes	N/A

Composition Analyzer						
	Measurement Method		**Near Infrared Photo Reflectance**	N/A	Near Infrared Photo Reflectance	N/A
	Transmitters		**Sequenced IR LEDs , > 750 nM**	N/A	Sequenced IR LEDs , > 750 nM	N/A
	Measurement Range		**3% - 45% Body Fat**	N/A	3% - 45% Body Fat	N/A
Galvanic Skin Resistance			**Yes**	N/A	N/A	Yes
	Measurement Method		**Constant Current Conductance**	N/A	N/A	Constant Current Conductance
	Sensor Type		**2 each 1x2 cm gold-plated brass**	N/A	N/A	2 each 1.0 cm^2 gold-plated brass
	Current Density		**1.5 uA per cm^2**	N/A	N/A	3.0 uA per cm^2
	Measurement Range		**1-100 Siemens**	N/A	N/A	0.8 – 50 Siemens
	Filtering		**3 pole Low Pass F_0 at 6 Hz**	N/A	N/A	12 Hz low pass, 18dB/oct
	Output Format		**Logarithmic 40 dB range**	N/A	N/A	A.C. logarithmic

Section 5: Performance Specification

The CWAS 100 specifications are summarized below:

EMG

Electrodes:	4 ea. Smart Sensors with low-noise preamplifiers integral to electrode assemblies
Calibrated Range:	0.1 – 999 uV
Input Bias Current:	Less than 2.0 Picoamperes
Differential Input Impedance:	Greater than 1,000,000 Megaohms
Common Mode Rejection:	150 dB
Bandwidth:	20-500 Hz (50/60 Hz notch)
Noise:	Less than 0.1 uV (inputs shorted)
Detector:	Log power detector, 250 mS averaging filter.
Controls:	None

Temperature

Calibrated Range:	55°F - 120°F
Accuracy:	±0.2°F nominal
Sensors:	Two thermopile, fixed 2.5" apart (center-to-center)
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 0.5" ABS Plastic Outer Ring.
Size:	5.5"L x 3.5"W x 2.5"H. Weight 15 oz.

IR Plethsmograph

Sensor Type	IR Plethsmograph (attached to finger with Velcro)
Output Voltage:	5 – 50 mV, typical at rest
Output Impedance:	1 kΩ, nominal
Weight:	28 grams
Sensor Size:	15 x 15 x6.3 mm

Galvanic Skin Resistance

Measurement Method:	Constant Current Conductance
Sensor Type:	2 each 1x2 cm gold-plated brass
Current Density:	1.5 uA per cm^2
Measurement Range:	1-100 Siemens
Filtering:	3 pole Low Pass F_0 at 6 Hz
Output Format:	Logarithmic 40 dB range

Futrex IR Body Composition Analyzer

Measurement Method:	Near Infrared Photo Reflectance
Sensor Type	Pin Photodiode
Transmitters:	Sequenced IR LEDs , > 750 nM
Measurement Range:	3% - 45% Body Fat
Dimensions:	2.3" diameter, and 0.8" height

Instrument Console

Inputs:	4 each EMG electrodes 1 each temperature sensor 1 each IR Plethsmograph sensor 1 each GSR sensor 1 each Futrex IR Body Composition sensor
Output:	Isolated USB
A/D converter:	16 bit, 16 channel
Controls:	None
Indicators:	Rear Panel: Green LED Power Indicator Front Panel: Green LED PC connect Indicator
Power:	12 VDC, 28 W converter, internal.
Physical:	Case Material: Impact resistant, flame retardant ABS. 3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz.

Section 6: Patient Safety

The CWAS 100 patient isolation is assured by the following two electrical isolation barriers:

1. Medical-Grade Universal Power Supply: This device is a UL2601 compliant AC line to 12 VDC, 28 W converter. This internal power supply is partitioned from all other circuitry via an earthed steel chassis. The power supply accepts 85-264 VAC, and 47-63 Hz via a IEC 60320 fused input module.

This supply provides low-level isolated power to the Non-Patient Side of the CWAS 100 circuitry, as well as power to the DC-to-DC isolation converter that powers to the Patient Side (see #2 below).

2. DC-to-DC Patient Isolation Converter: This converter is a UL2601 compliant DC-to-DC converter, and meets the dielectric withstand and leakage current requirements of the UL2601 standard for Patient Care Equipment with isolated patient leads.

   This converter supplies all power to patient-applied parts and related circuitry. Each of the direct patient-applied parts have individual current limiters for fault condition.

In addition, the Patient Side of the CWAS 100 is isolated from the host PC as follows:

3. Optically Isolated Data Link: Signals are converted from analog voltages to 16 bit digital values by the analog-to-digital converter (ADC). The digital data is sent to and from the USB of the PC across an optically isolated data link.

   This optical link is UL2601 compliant, providing the dielectric withstand and low leakage current characteristics specified in UL2601.

Section 7: Conclusion

The CWAS 100 is substantially equivalent to the predicate devices. Furthermore, the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2003

Fasstech
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Avenue S.E.
Grand Rapids, Michigan 49548

Re: K033452
Trade/Device Name: CWAS 100
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: IKN
Dated: November 13, 2003
Received: November 14, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033452

Device Name: CWAS 100

Indications for Use:

The CWAS 100 is a non-invasive, multi-modality physiologic monitoring device. The device measures several physiologic signals, and its software generates a report.

The CWAS 100 measures the following physiologic signals:

- Bilateral differences in surface EMG along the spine
- Heart Rate
- Skin temperature
- Galvanic Skin Resistance
- Body fat percentage in subjects eighteen years and older

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033452